NUCLEAR ENERGY INSTITUTE

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U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

SUBJECT: Resolution of ESP-3 (Quality Assurance Requirements for ESP Applications)

In public meetings on April 24, May 28, June 13, October 17, and December 5, 2002, we discussed generic early site permit topic ESP-3, which concerns the ambiguity in existing regulations regarding the quality assurance (QA) requirements governing ESP applications and reviews.

Enclosure 1, previously provided to the NRC staff on November 20, discusses the industry perspective; Enclosure 2 provides the staff position as presented during our discussion of this topic on December 5. The industry and NRC staff papers and our December 5 discussions reflect a convergence of views with respect to the QA requirements for ESP. In accordance with the protocol established for documenting resolution of generic ESP issues, we request that, by reply to this letter, the NRC confirm the understandings and expectations identified below that resulted from these interactions. To provide for timely resolution of generic issues and continued progress toward submittal of ESP applications in mid-2003, we request that NRC respond by February 1, 2003.

ESP-3 understandings and expectations:

1. Each pilot ESP applicant is implementing effective quality processes to (1) support the completeness and accuracy of information contained in ESP applications as required by 10 CFR 50.9, and (2) provide an overall level of quality that facilitates timely and efficient ESP application review by the NRC. ESP applicant quality processes will provide confidence in the quality of ESP information, including that which might be used as an input to the design or analysis of safety significant structures, systems and components (SSCs) as part of a future COL application (e.g., collection and analysis of certain seismic and meteorological data).

ESP applicants are not required to have a 10 CFR Part 50, Appendix B, QA program. ESP applicants may apply quality controls/procedures consistent with relevant Appendix B criteria, or applicants may apply alternative quality processes. Quality elements that will be applied to preparation of ESP information that may be used as design inputs for safety significant SSCs or safety analyses include:

- Quality plan and procedures
- Data quality and pedigree
- Data analysis quality
- Oversight
- Recordkeeping

2. There is no regulatory requirement for pre-application review by NRC of an ESP applicant's quality processes; however, such reviews may be beneficial to in facilitating timely and efficient completion of ESP application reviews.

3. In response to an NRC request, each pilot ESP applicant has agreed to submit a description of its quality processes for NRC staff pre-application review and feedback. In response to similar future requests by NRC, submittal of quality process information for NRC pre-application review is at the discretion of future ESP applicants.

4. Pre-application interactions, including review of ESP applicant QA processes, are expected to minimize the need for further NRC review of QA processes after ESP applications are submitted and allow ESP application reviews to focus on the completeness, accuracy and overall quality of the technical information provided by the ESP applicants.

5. Based on our December 5th discussions, we understand that the term "baseline for use" in the November 19 staff position refers to the future use of the ESP site safety information in a COL application, not to the future use of the ESP QA processes for COL activities. The industry recognizes that COL activities would be subject to 10 CFR Part 50 Appendix B, as appropriate.

6. ESP applicants may, but are not required by Section 52.17 to describe their quality assurance programs in their ESP applications. Regulations clearly require submission of complete and accurate information (e.g., 10 CFR 50.9), and ESP applications will be submitted under oath and affirmation as required by 10 CFR 50.30(b), and as discussed in NRC Regulatory Issue Summary 2001-18.

7. Because of the finality of the issues resolved as part of the ESP process, the staff must have confidence in the site safety analyses information in order to make its conclusions. It is expected that the NRC staff will review the applicant's quality processes and sources of information to develop the necessary confidence in ESP information.

We expect that upon confirmation, these understandings and expectations, including clarifications deemed appropriate by the NRC staff, would be integrated into the ESP inspection guidance and the ESP review standard currently under development by the staff. Detailed comments on IMC-2501, dated October 8, 2002, will be provided separately.

Enclosure 3 provides for information an updated listing and status of generic ESP topics.

We look forward to your confirmation of the understandings and expectations described above related to ESP-3, and your response to the additional industry view concerning QA program requirements for ESP. If you have any questions concerning this request, please contact me (202-739-8128 or rls@nei.org) or Russ Bell (rjb@nei.org or 202-739-8087).

Sincerely,

Original Signed By:

Ron Simard

Enclosures

c: Ronaldo V. Jenkins, NRC/NRR
Document Control Desk

GENERIC TOPIC ESP-3
NEI WHITE PAPER ON QA REQUIREMENTS FOR ESP

Introduction

One of the first generic issues identified with respect to plans for preparation, submittal and review of first-ever ESP applications concerned the quality assurance processes to be applied to ESP activities. The industry indicated the view that NRC regulations did not mandate use of 10 CFR Part 50, Appendix B, for ESP and thus that either Appendix B or alternative quality processes could be applied. While disagreement on this fundamental point was not immediately evident, recent statements by the NRC make clear the staff expectation that Appendix B is applicable for ESP and that ESP applications would be reviewed for compliance with Appendix B. This paper describes our basis for concluding that Appendix B is neither required nor necessary for ESP and thus that applicants may apply either Appendix B or alternative quality processes to their ESP activities.

Summary of Issue

As expressed in our public meetings, and most recently on October 17, ESP applicants are committed to implementing effective quality processes to provide adequate confidence in the completeness, accuracy and general quality of ESP information to facilitate efficient ESP application review by NRC. It is the industry's view that to achieve these objectives, ESP applicants may apply 10 CFR Part 50, Appendix B, or they may apply non-Appendix B alternative quality processes. We hold this view because Appendix B is neither required for ESP by NRC regulations nor necessary for assuring quality. Moreover, if non-Appendix B alternative quality processes are used, NRC review of ESP applications for compliance with Appendix B would not be expected and justifications for departures from specific Appendix B requirements, Regulatory Guides, and ASME NQA-1 would not be required.

Contrasting with this view are NRC staff statements made in discussions with NEI and the pilot ESP applicants, as well as in recently released IMC-2501. These statements reflect the view that ESP applications are subject to Appendix B and would be reviewed for compliance with Appendix B. Notwithstanding these statements, the NRC staff has acknowledged that the applicability of Appendix B to ESP is currently under review by the Office of General Counsel.

The acceptability of using either Appendix B or alternative quality processes is an important unresolved issue for ESP applicants. Clarification of QA program requirements for ESP is needed as quickly as possible to support ongoing preparations of ESP applications.

The following is a summary of our basis for concluding that Appendix B is not necessary to assure quality and by its terms does not apply to ESP activities. More detailed discussion of the industry view is provided following the summary.

1. ESP activities are not within the scope of Appendix B. By its terms, Appendix B establishes quality assurance requirements for the design, fabrication, construction, testing and operation of nuclear plant structures, systems and components (SSCs) that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public. Appendix B applies to the activities affecting the safety-related functions of those SSCs. ESP includes no such activities.

2. While NRC regulations explicitly state that applications for Construction Permits, Operating Licenses, Design Certifications and Combined Licenses are subject to Appendix B, Section 52.17, *Contents of* [ESP] *Applications*, does not specify QA requirements for ESP applications.

3. 10 CFR Part 52, Subpart A, contains the following requirements:

   - Section 52.18, *Standards for review of applications*, specifies that ESP applications "will be reviewed according to the *applicable standards* set out in 10 CFR Part 50 and its appendices and Part 100 as they apply to applications for construction permit for nuclear power plants." [Emphasis added.]

     and,

   - Section 50.34(a)(7) requires construction permit applications to include "a description of the quality assurance program to be applied to the *design, fabrication, construction and testing of the structures, systems and components of the facility,*" (Emphasis added) and further that the QA program description "include a discussion of how the applicable requirements of Appendix B will be satisfied."

   However, contrary to the NRC staff conclusion in IMC-2501, the requirement for construction permit applications to include Appendix B-compliant QA program descriptions is not an "applicable standard" for review of ESP applications because ESP activities do not include facility design, fabrication, construction or testing.

4. Consideration of an ESP as a "partial construction permit" in Sections 52.21 and 52.37 is for the specific purposes of defining, respectively, required hearing procedures and reporting of defects. Considering an ESP as a "partial construction permit" for these specific purposes does not impose all the requirements for a construction permit on an ESP. In particular, it does not impose Appendix B quality assurance requirements on ESP applicants through either Sections 52.18 or 50.55(f)(1).

5. Lack of specific QA requirements is consistent with scope of ESP activities and the distinction recognized in Part 100 between siting activities and those related to design, construction, testing and operation.

6. Notwithstanding the absence of specific quality assurance program requirements for ESP, the completeness and accuracy of ESP applications are assured by 10 CFR 50.9 (which requires that licensing submittals to NRC be complete and accurate in all material respects), and by quality processes employed by the applicant. Completeness and accuracy are further promoted by use of NRC Regulatory Guides and Standard Review Plans that outline methods and sources of data acceptable to the staff for the technical information provided in the ESP.

As previously discussed, the pilot ESP applicants are implementing effective quality processes (1) in furtherance of their obligation to provide complete and accurate information pursuant to 10 CFR 50.9, and (2) to provide an overall level of quality that facilitates efficient ESP application review by the NRC.

To promote understanding of ESP applicant quality processes and facilitate timely and efficient ESP application reviews by the NRC staff, pilot ESP applicants are providing a description of their quality processes to NRC for pre-application consideration and feedback. Future ESP applicants may do likewise.

Summary of industry views regarding QA requirements for ESPs

- ESP applicants may apply Appendix B or non-Appendix B alternative quality processes to provide adequate confidence in the completeness, accuracy and overall quality of ESP information

- ESP applicants may, but are not required by Section 52.17 to describe their quality processes in ESP applications.

- The NRC should review ESP applications for completeness and accuracy of the information presented. Unless the ESP applicant commits to use Appendix B, NRC reviews for compliance with Appendix B would not be appropriate.

- ESP information approved by the NRC is appropriate for use in a COL application as provided by 10 CFR Part 52, Subpart C.

- Existing NRC guidance, including IMC-2501, should be modified, and forthcoming ESP Review Standard should reflect that Appendix B is not mandatory for ESP related activities

Our November 20 submittal also included the following complete discussion of the industry views summarized above.

Industry White Paper on Generic Topic ESP-3
Quality Assurance Requirements for an ESP Application

Summary of Issue

As expressed in our public meetings, and most recently on October 17, ESP applicants are committed to implementing effective quality processes to provide adequate confidence in the completeness, accuracy and general quality of ESP information to facilitate efficient ESP application review by NRC. It is the industry's view that to achieve these objectives, ESP applicants may apply 10 CFR Part 50, Appendix B, or they may apply non-Appendix B alternative quality processes. We hold this view because Appendix B is neither required for ESP by NRC regulations nor necessary for assuring quality. Moreover, if non-Appendix B alternative quality processes are used, NRC review of ESP applications for compliance with Appendix B would not be expected and justifications for departures from specific Appendix B requirements, Regulatory Guides, and ASME NQA-1 would not be required.

Contrasting with this view are NRC staff statements made in discussions with NEI and the pilot ESP applicants as well as in recently released IMC-2501. These statements reflect the view that ESP applications are subject to Appendix B and would be reviewed for compliance with Appendix B and associated Regulatory Guides, ANSI Standards, ASME NQA-1, etc. Notwithstanding these statements, the NRC staff has acknowledged that the applicability of Appendix B to ESP is currently under review by the Office of General Counsel.

The acceptability of using either Appendix B or alternative quality processes is an important unresolved issue for ESP applicants. Clarification of QA program requirements for ESP is needed as quickly as possible to support ongoing preparations of ESP applications.

The following sets forth with more particularity our basis for concluding that Appendix B is not necessary to assure quality and by its terms does not apply to ESP activities.

1. ESP applicants are not required by 10 CFR Part 52, Subpart A, to submit a quality assurance program or program description in support of an ESP application.

Numerous sections within Title 10 require the submittal of a Quality Assurance (QA) Program Description (QAPD) in connection with certain licensing activities. For example, a QAPD submittal is expressly required to be included for the Preliminary Safety Analysis Report in accordance with 50.34(a)(7) for a construction permit application, and in the Final Safety Analysis Report in accordance with 50.34(b)(6) for an operating license application.

Similarly, Section 52.47 requires an application for design certification to include "the technical information which is required of applicants for construction permits and operating licenses by 10 CFR Part 20, Part 50 and its appendices, and Parts 73 and 100, and which is technically relevant to the design and not site-specific." The specific requirement to include the technical information required by Part 50 and its appendices includes both the references to 50.34(a)(7) and 50.34(b)(6); thus a QAPD is clearly required for a design certification application under Subpart B of Part 52. This requirement is appropriate since the development of a design certification application involves design activities that are clearly within the scope of Appendix B QA criteria.

Finally, Section 52.79 requires an application for a combined license to include "the technically relevant information required of applicants for an operating license by 10 CFR 50.34." This also includes both the references to 50.34(a)(7) and 50.34(b)(6); thus a QAPD is clearly required for a combined license application under Subpart C of Part 52. This requirement is similarly appropriate since the combined license activities also include design as well as a construction and operation activities that are clearly within the scope of Appendix B QA criteria.

No express provision for a QAPD is contained within Subpart A of Part 52. Section 52.17 states that an ESP application shall consist of a site safety assessment, an environmental report, emergency planning information, and under some conditions not pertinent to this issue, a site redress plan. It does not require a QAPD to be a part of the application. Each of the other above-mentioned licensing activities expressly requires the inclusion of the QAPD information required by 50.34. However, the Early Site Permit application requirements of 52.17 do not include a reference that includes either 50.34(a)(7) or 50.34(b)(6). Accordingly, no QAPD is required to be submitted with an Early Site Permit application. Not requiring a QAPD for the ESP application is appropriate since no design, construction, or operation activities are being carried out during this phase of the licensing process.

2. Section 52.18, *Standards for review of applications*, does not expand the required contents of ESP applications

As discussed above, there is no express provision within Subpart A requiring a QAPD to be submitted with an ESP application. The Staff, as set forth in its recently issued Inspection Manual Chapter (IMC) 2501, seeks to require a QAPD through Section 52.18, *Standards for review of applications,* which invokes provisions set forth for Construction Permits, including Section 50.34(a)(7)[1].

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[1] 10 CFR 50.34(a)(7) requires:
A description of the quality assurance program to be applied to the design, fabrication, construction and testing of the structures, systems, and components of the facility. Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," sets forth the requirements for quality assurance programs for nuclear power plants and fuel reprocessing plants. The description of the quality assurance program for a nuclear power plant or fuel reprocessing plant shall include a discussion of how the applicable requirements of appendix B will be satisfied.

Section 03.11 of the NRC IMC 2501 identifies the "Tendered/Docketed Application" consistent with 10 CFR 52.17. However, Section 05.05 titled "Quality Assurance" presumes that Section 52.18 somehow extends Section 52.17 to require the submittal of a QAPD.

Section 05.05 reads (in part):

> "10 CFR 52.18 requires that applications filed under Part 52 be reviewed according to the applicable standards set out in 10 CFR Part 50 and its appendices and Part 100 as they apply to applications for construction permits for nuclear power plants. Section 50.55, 'Conditions of a Construction Permit' states in (f)(1) that each construction permit holder subject to the QA criteria in appendix B shall implement, pursuant to 50.34(a) a QA plan. 10 CFR 50.34 states that an applicant is required to submit a QA program description discussing how the applicable requirements of Appendix B will be satisfied. Accordingly, those portions of the ESP application which are applicable to the requirements of 10 CFR Part 50 Appendix B will be inspected and reviewed pursuant to Appendix B (and if provided with the ESP application), the QA program description. The quality associated with those parts of the ESP application not applicable to Appendix B will be reviewed to recognized industry codes and standards."

While 52.18 identifies the criteria for the NRC staff to review and evaluate the information provided in the application per 52.17, it does not extend those requirements such that additional information not identified in 52.17 must be included in the application. Using logic as applied in Section 05.05 of IMC 2501, all informational provisions of 50.34 would be required to be submitted with an ESP application. There is no indication in the regulations that this blanket application of section 50.34 was intended by sections 52.17 or 52.18.

The NRC staff has cited the Subpart A characterization of an ESP as a "partial construction permit" as basis for broadly applying construction permit standards and conditions to ESP applications as indicated in Section 05.05 of IMC 2501. The regulations indicate that an ESP is considered a partial construction permit, but only for the purposes of Part 21 and 50.100 (see section 52.37[2]) and for the purposes of procedural requirements of 10 CFR Part 2 (see section 52.21[3]). These specific limitations to the scope of the ESP application as a construction permit clearly demonstrate a desire not to impose all of the requirements for a construction permit

[2] 10 CFR § 52.37, " Reporting of Defects and non-compliance; revocation, suspension, modification of permits for cause", states: "For purposes of part 21 and 10 CFR 50.100, an early site permit is a construction permit."

[3] 10 CFR § 52.21, "Hearings" states in pertinent part:
An early site permit is a partial construction permit and is therefore subject to all procedural requirements in 10 CFR part 2 which are applicable to construction permits, including ... docketing ..., and notice of hearing."

on an ESP. This proposition is further supported by the language of § 52.25, "Extent of activities permitted", which limits activities to be accomplished by an ESP holder to only those non-safety related activities allowed by 10 CFR 50.10(e)(1).[4] These distinctions to and limitations of the application of construction permit requirements demonstrate the intent that not all construction permit requirements are applicable to an ESP.[5]

Section 05.05 continues in pertinent part by stating that "the application should provide an adequate basis for evaluation of the acceptability of the QA program implementation" and "the inspector will review the description of the QA program provided in the application...." As indicated above, these are also extensions of § 52.17 without regulatory basis. There is no requirement for a QAPD to be included in an ESP application.

3. Appendix B to 10 CFR Part 50 is not mandatory for ESP activities, and therefore ESP applicants may apply Appendix B, or they may apply non-Appendix B alternative quality processes.

10 CFR 50.34(a)(7) requires, as part of the preliminary safety analysis report:

> *"A description of the quality assurance program to be applied to the design, fabrication, construction, and testing of the structures, systems, and components of the facility.* Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," sets forth the requirements for quality assurance programs for nuclear power plants and fuel reprocessing plants. *The description of the quality assurance program for a nuclear power plant or a fuel reprocessing plant shall include a discussion of how the applicable requirements of appendix B will be satisfied."* [Emphasis added]

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[4] 10 CFR § 50.10(e)(1) permits:
This regulation provides for conduct of "the following activities: (i) Preparation of the site for construction of the facility (including such activities as clearing, grading, construction of temporary access roads and borrow areas); (ii) installation of temporary construction support facilities (including such items as warehouse and shop facilities, utilities, concrete mixing plants, docking and unloading facilities, and construction support buildings); (iii) excavation for facility structures; (iv) construction of service facilities (including such facilities as roadways, paving, railroad spurs, fencing, exterior utility and lighting systems, transmission lines, and sanitary sewerage treatment facilities); and (v) the construction of structures, systems and components which do not prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public."

[5] This proposition is further reinforced by section 50.55(a), which requires the "permit shall state the earliest and latest dates for completion of the construction or modification." This is clearly not applicable to an ESP since no construction or modification is allowed by an ESP (per 52.25). Similarly, 50.55(f)(1) is not applicable to an ESP since as indicated above, no quality assurance program is [required to be] described or referenced in the Safety Analysis Report. Again, §50.34(a)(7) is not referenced in §52.17; thus no QAPD is required to be included in the ESP application.

As indicated in 50.34(a)(7) the quality assurance requirements for nuclear power facilities are identified in Appendix B to 10 CFR Part 50. The introduction to Appendix B is repeated below.

> *"Introduction.* Every applicant for a construction permit is required by the provisions of §50.34 to include in its preliminary safety analysis report a description of the quality assurance program to be applied to the design, fabrication, construction, and testing of the structures, systems, and components of the facility. Every applicant for an operating license is required to include, in its final safety analysis report, information pertaining to the managerial and administrative controls to be used to assure safe operation. Nuclear power plants and fuel reprocessing plants include structures, systems, and components that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public. This appendix establishes quality assurance requirements for the design, construction, and operation of those structures, systems, and components. The pertinent requirements of this appendix apply to all activities affecting the safety-related functions of those structures, systems, and components; these activities include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying.
>
> "As used in this appendix, 'quality assurance' comprises all those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service. Quality assurance includes quality control, which comprises those quality assurance actions related to the physical characteristics of a material, structure, component, or system which provide a means to control the quality of the material, structure, component, or system to predetermined requirements."

Note that this requirement indicates that the "appendix establishes quality assurance requirements for the *design, construction, and operation* of those structures, systems, and components" and that the "pertinent requirements of this appendix *apply to all activities affecting the safety-related functions of those structures, systems, and components*." The NRC Staff has cited this latter statement to expand beyond the stated "design, construction, and operation" activities. However, the introduction further clarifies that "these activities include *designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying.*" (emphasis added) Site characterization activities are not identified. Similarly, the 10 CFR 50.34(a)(7) requirement is for a description of "*the quality assurance program to be applied to the design, fabrication, construction, and testing of the structures, systems, and components of the facility.*" Note that, like Appendix

B, this requirement is also limited to design, fabrication, construction, and testing activities.

The industry does not disagree that Appendix B is applicable to design, construction, and testing activities for structures, systems, and components (SSC) that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public. However, because the scope of the ESP application does not include the design, construction or testing of such "safety-related" SSCs, Appendix B is not applicable to ESP activities.

4. **The lack of specific QA requirements for ESP and the acceptability of applying Appendix B or alternative non-Appendix B quality processes are consistent with the limited scope of ESP activities and the recognized distinction between siting factors and those related to design, construction, testing and operation.**

The requirements of 10 CFR Part 52, Subpart A, provide for "approval of a site or sites for one or more nuclear power facilities separate from the filing of an application for a construction permit or combined license for such a facility" (see 52.11). Such approval is provided in an Early Site Permit and is based primarily on the identification of site characteristics (which comply with Part 100, "Reactor Site Criteria,") in a safety analysis report and acceptable environmental impacts as identified in an environmental report. These site characteristics will then be used as design input when the safety-related design process begins for any future facility to be constructed on the site.

Note the distinction between "design process" and the "design input." The NQA-1 (1983) standard, Quality Assurance Program Requirements for Nuclear Facilities (as endorsed by Regulatory Guide 1.28, Quality Assurance Program Requirements (Design and Construction)), contains the following definitions and other pertinent statements:

- **Design process (definition)**: technical and management processes that commence with identification of design input and that lead to and include the issuance of design output documents.

- **Design input (definition)**: those criteria, parameters, design bases, regulatory requirements, or other design requirements upon which detailed final design is based.

- "Applicable design inputs shall be identified and documented, and their selection reviewed and approved." [Section 3 (200)]

- "Documentation of design analyses shall include... (b) design inputs and their sources." [Section 3 (402)]

- "Design inputs include many characteristics and functions of an item or system," including: "(e) loads such as seismic, wind, thermal and dynamic... and (f) environmental conditions anticipated during storage, construction, operation, and accident conditions, such as pressure, temperature, humidity, corrosiveness, site elevation, wind direction, exposure to weather, flooding, ..." [Appendix 3A-1 (200)]

Each of the above statements has been consistently included in appropriate standards since ANSI N45.2.11 (1974), *Quality Assurance Requirements for the Design of Nuclear Power Plants.*

Thus, the selection of design inputs (at COL application stage) would be included in the design process; however, the determination/development of the design inputs (at the ESP application stage) would not be included in the design process. Since Appendix B does not apply until the design process begins, Appendix B is not applicable to ESP stage activities under the "design" activities criterion.

Consideration of site characteristics as design inputs is also consistent with their treatment in 10 CFR Part 52, Subpart B, for standard design certification. Site parameters are identified as design inputs to determine the acceptability of the design as identified in SRP 14.3.1 (draft Rev. 0, April 1996).

The distinction between siting activities versus design, construction, and operation is also recognized in the Purpose section (§100.1) of Part 100, "Reactor Site Criteria". The requirements of 10 CFR Part 100 begin:

> "(a) The purpose of this part is to establish approval requirements for proposed sites for stationary power and testing reactors subject to part 50 or part 52 of this chapter.
>
> (b) There exists a substantial base of knowledge regarding power reactor siting, design, construction, and operation. This base reflects that the primary factors that determine public health and safety are the reactor design, construction and operation.

(c) Siting factors and criteria are important in assuring that radiological doses from normal operation and postulated accidents will be acceptably low, that natural phenomena and potential man-made hazards will be appropriately accounted for in the design of the plant, that site characteristics are such that adequate security measures to protect the plant can be developed, and that physical characteristics unique to the proposed site that could pose a significant impediment to the development of emergency plans are identified.

(d) This approach incorporates the appropriate standards and criteria for approval of stationary power and testing reactor sites. The Commission intends to carry out a traditional defense-in-depth approach with regard to reactor siting to ensure public safety. Siting away from densely populated centers has been and will continue to be an important factor in evaluating applications for site approval."

Section (a) indicates that the "purpose of this part is to establish approval requirements for proposed sites for stationary power and testing reactors subject to part 50 or part 52 of this chapter." However, Part 100 does not identify Appendix B to 10 CFR Part 50 as one of those requirements.

Section (b) indicates an NRC differentiation between power reactor siting activities and the power reactor activities of design, construction, and operation. It clearly notes "*the primary factors that determine public health and safety are the reactor design, construction and operation.*" Appendix B to 10 CFR Part 50 indicates clearly that it "establishes quality assurance requirements for the design, construction, and operation of those structures, systems, and components" that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public. It does not mention siting activities, and Part 100 does not indicate siting is considered as a primary factor.

Section (c) does indicate that "siting factors and criteria are important" in radiological dose considerations, in the design of the plant, in security, and in emergency planning. Section (d) then indicates "this approach incorporates the appropriate standards and criteria for approval of stationary power and testing reactor sites." Again, this approach, i.e., Part 100, does not identify Appendix B to 10 CFR Part 50 as one of "the appropriate standards and criteria for approval of stationary power and testing reactor sites."

Further, Part 100 clearly indicates the investigations required for geological, seismological, and engineering characteristics described in Part 100 are within the scope of investigations permitted by §50.10(c)(1) of this chapter. Specifically, §100.23(b) clearly states "The investigations required in paragraph (c) of this section [Geological, seismological, and engineering characteristics] are within the scope of investigations permitted by § 50.10(c)(1) of this chapter." The activities permitted by §50.10(c)(1) are identified therein as "borings... or other pre-construction monitoring to establish background information related to the suitability of the site or to the protection of environmental values." Such activities, i.e., those permitted by §50.10(c)(1), while conducted in a quality manner, have historically been conducted outside the purview of a formal Appendix B quality assurance program.

While granting of an ESP may include authorization of preliminary construction activities under Section 52.25, the "extent of activities permitted" limits activities to those allowed by 10 CFR 50.10(e)(1). This regulation provides for conduct of "the following activities" under an ESP:

> "(i) Preparation of the site for construction of the facility (including such activities as clearing, grading, construction of temporary access roads and borrow areas); (ii) installation of temporary construction support facilities (including such items as warehouse and shop facilities, utilities, concrete mixing plants, docking and unloading facilities, and construction support buildings); (iii) excavation for facility structures; (iv) construction of service facilities (including such facilities as roadways, paving, railroad spurs, fencing, exterior utility and lighting systems, transmission lines, and sanitary sewerage treatment facilities); and (v) the construction of structures, systems and components which do not prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public."

These activities have historically not fallen under the Appendix B "construction" activities criterion.

5. **The ESP pilot applicants are implementing quality processes to provide adequate confidence in the completeness, accuracy and general quality of ESP information. Quality assurance practices that provide a complete and accurate ESP application are sufficient.**

Because NRC regulations do not require the use of Appendix B, ESP applicants may apply 10 CFR Appendix B or alternative quality processes to provide adequate confidence in the completeness, accuracy and general quality of ESP information to facilitate efficient ESP application review by NRC.

Unless an applicant commits to use Appendix B, it would be inappropriate to review ESP applications for compliance with Appendix B or to require justification for departures from specific Appendix B criteria.

NRC can and should verify quality of ESP application field data, input, and evaluations through technical review of the application. It is expected that quality would also be verified through audit of both the data collection and analysis processes (to identified and accepted industry standards) and of the implementation of alternative or augmented quality processes. Such reviews and audits can also be used to verify the information is accurate and complete in conformance with §50.9 requirements.

NRC Inspection Manual Chapter 2501 appropriately states in §05.05, "the quality and pedigree associated with those parts of the ESP application not applicable to Appendix B will be reviewed to recognized industry codes and standards." This would provide an appropriate basis for evaluating an ESP application .

Appendix B was developed to provide the minimum acceptable standards for "structures, systems, and components that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public." While appropriate for such SSCs, these standards typically result in a significant increase in the expenditure of resources, both time and money. This higher standard is not necessary for determining site characteristics or performing environmental studies and associated evaluation activities to provide sufficient confidence in the results. Acceptability of non-Appendix B alternative quality processes is consistent with NRC guidance on quality assurance in several important areas, including

- Regulatory Guide 4.15, on radiological monitoring of effluent streams and the environment for normal operations
- Regulatory Guide 1.97, on requirements for design and use of post-accident instrumentation
- Regulatory Guide 1.176, which recommends augmented non-Appendix B quality assurance for non-safety-related equipment that may be of high safety significance
- Generic Letter 85-06, which provides quality assurance guidance for ATWS equipment
- Regulatory Guide 1.155, which provides quality assurance guidance for station blackout equipment
- Regulatory Guide 1.189 and Branch Technical Position 9.5-1, which provide quality assurance guidance for fire protection equipment

It is important to differentiate between §50.9 requirements for complete and accurate information and the Appendix B to 10 CFR Part 50 requirements for SSC design, construction, and operation activities. These are separate requirements for separate activities. Complete and accurate information does not ensure a quality pedigree for design, construction, and operation activities. Similarly, quality processes for design, construction, and operation activities do not provide any assurance that the information in a submittal to NRC will be complete and accurate. Either can be met or violated without effect on the other.

6. **Existing NRC guidance, including IMC-2501, should be modified, and the forthcoming ESP review standard should reflect, as described above, that Appendix B is not mandatory for ESP related activities, and specifically that**

- ESP applicants may apply Appendix B or non-Appendix B alternative quality processes to provide adequate confidence in the completeness, accuracy and overall quality of ESP information

- ESP applicants may, but are not required by Section 52.17 to describe their quality processes in ESP applications.

- The NRC should review ESP applications for completeness and accuracy of the information presented. Unless the ESP applicant commits to use Appendix B, NRC reviews for compliance with Appendix B would not be appropriate.

- ESP information approved by the NRC is appropriate for use in a COL application as provided by 10 CFR Part 50, Subpart C.

ESP-3, Enclosure 2
December 20, 2002

ESP-3 Quality Assurance (QA) Requirements for an ESP Application

NRC staff position presented during December 5, 2002, public meeting)

Issue: Industry has advanced the position that ESP may apply 10CFR Part 50, Appendix B, or they may apply non-Appendix B alternative quality processes. (see associated White Paper on ESP-3)

Staff Position: The staff is required under 10 CFR 52.18, Standards for review of applications, to review ESP applications according to the applicable standards set out in 10 CFR Part 50 and its appendices as they apply to construction permits under Part 50. The applicable ESP review areas are site safety, environmental impact and emergency preparedness. As noted in the Industry White Paper, appropriate quality assurance is necessary in order to facilitate efficient staff review. The staff does not hold that ESP applicants are required to have an Appendix B Program.

The staff intends to assess the ESP applicant's QA program to ensure that the appropriate QA elements are in place in order (1) to establish a baseline for future use during the COL process and (2) to assess any potential impact on the staff's findings. For example, we will use Appendix B to guide us in the assessment of the quality assurance used to develop site safety application information.

The site safety review area contains information (i.e., analyses, data) materially important to the satisfactorily performance of safety-related structures, systems and components (SSCs) for a future reactor or reactors to be operated without undue risk to the health and safety of the public at the subject site. Because of the finality of the issues resolved as part the ESP process, the staff must assure as part of our review that the appropriate quality assurance elements for the site safety information are in place consistent with a comparable review of a construction permit applicant.

So to summarize, the staff intends to assess the ESP applicant's QA program to ensure that the appropriate QA elements are in place in order (1) to establish a baseline for future use during the COL process and (2) to assess any potential impact on the staff's findings. The staff will utilize Appendix B as necessary in order to guide us in that assessment.

ESP-3 – Enclosure 3
December 20, 2002

Status of Generic ESP Interactions

ESP Topic Higher priority topics shaded	Initial Discussion	Resolution Pending	Discussions Ongoing	Next Discussion	NEI Letter	NRC Response	Potential Snr. Mgmnt Issue	ESP Schedule Impact if not Resolved by	Remarks
1. ESP application form & content	8/22		x	1/29					NRC provided TOC comparison on Oct. 16
2. ESP inspection guidance	4/24		x	1/29					• IMC-2501 issued; reflects QA open issue (see ESP-3) • ESP Review Std to be issued for use & comment by year end
2a. Pre-application interactions (voluntary nature, plans for local public mtgs & review fee structure)	4/24	x			11/26				
3. QA requirements for ESP information	5/28	x			12/20			2/1/03	
4. Nominal NRC review timeline	10/17		x	1/29					
5. Mechanism for documenting resolution of ESP issues	5/28				9/10	11/5			
6. Use of plant parameters envelope (PPE) approach	7/16	x			12/20			2/1/03	
7. Guidance for satisfying §52.17(a)(1) requirements	7/16	x			12/20			2/1/03	Related to ESP-6
8. Fuel cycle and transportation impacts (Tables S-3 & S-4)	9/25		x	1/29				3/1/03	
9. Criteria for assuring control of the site by the ESP holder				3/5					
10. Use of License Renewal GEIS for ESP	9/25	x							
11. Criteria for determining ESP duration (10-20 years)	12/5	x			12/20				

ESP Topic Higher priority topics shaded	Initial Discussion	Resolution Pending	Discussions Ongoing	Next Discussion	NEI Letter	NRC Response	Potential Snr. Mgmnt Issue	ESP Schedule Impact if not Resolved by	Remarks
12. Guidance for evaluating severe accident mitigation alternatives under NEPA	8/22	x			12/20			2/1/03	
13. Guidance for ESP seismic evaluations	6/13		x	1Q03					2nd meeting on pilot demonstration activity planned for 1Q03
14. Applicability of Federal requirements concerning environmental justice				3/5					Evaluating related PFS decision by Commission
15. Appropriate level of detail for site redress plans	9/25	x			11/26				
16. Guidance for ESP approval of emergency plans				1/29					
17. Petition to eliminate duplicative NRC review of valid existing site/facility information									Staff recommendation pending on petition PRM-52-1
18. Petition to eliminate reviews for alternate sites, sources and need for power									Staff recommendation pending on petition PRM-52-2
18a Alternative site reviews	12/5	x			12/20			3/1/03	
19. Addressing effects of potential new units at an existing site				3/5					
20. Practical use of existing site/facility information	9/25	x			11/26				
21. Understanding the interface of ESP with the COL process.				3/5					
22. Form and content of an ESP	8/22		x	1Q03				2/1/03	NEI draft under consideration by NRC